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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
LIU, SUE XU	

ART UNIT	PAPER NUMBER
1639	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/811,331	LAM ET AL.	
	Examiner	Art Unit	
	Sue Liu	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *8-11,13,14,19 and 21-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,12,15-18,20 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

1. Claims 1-29 are currently pending.

2. Claims 8-11, 13, 14, 19 and 21-28 have been withdrawn.

Claims 1-7, 12, 15-18, 20 and 29 are being examined in this application.

Election/Restrictions

3. Applicant's election with traverse of Group I (Claims 1-21 and 28) in the reply filed on 11/27/06 is acknowledged. The traversal is on the ground(s) that "the Patent Office conjecture is insufficient evidence to support such a restriction" (Reply, p. 15, para 4). This is not found persuasive because applicants have made the above argument without specifically pointing to the reasons why there is lack of support for a proper restriction. Contrary to applicant's assertion, the previous Restriction Requirement provided sufficient support for restricting the claimed inventions (see Restriction Requirement, mailed 9/28/06, pp. 2+). Applicants further argue that there would be no serious search burden to search all the groups because "the claims of Groups I-V encompass a single inventive concept" (Reply, p. 15). The concept of unity of invention is the restriction practice under PCT rules, and applies to applications filed under 35 U.S.C. 371. The instant application is not filed under 35 U.S.C. 371.

Furthermore, the different inventions as grouped have separate classifications, and are distinct for the reasons discussed in the previous sent Restriction Requirement, mailed 9/28/06, pp. 2+. These distinct inventions would require different searches in each of the respective

classes and/or subclasses. The searches required for each group are not co-extensive thus requiring a burdensome search. Additionally, different patentability considerations are involved for each group. These considerations are very different in nature.

The requirement is still deemed proper and is therefore made FINAL.

4. Claims 22-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/27/06.

5. Applicant's election of species as specified in the Reply filed on 11/27/2006 (Reply, p. 12+) and 4/9/07 (p. 11+) is acknowledged. Applicants elected the following species:

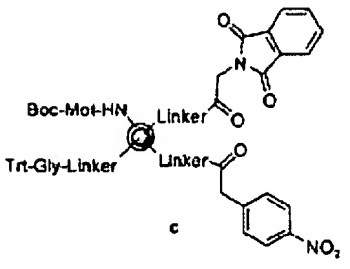
a.) TentaGel resin bead as solid support;

b.) Fmoc-linker as reactive functional group;

c.) Boc as exterior reactive groups;

d.) two coding tag precursor: phthaloylglycine and 4-nitrophenylacetic acid;

e.) synthesis template:



f.) first reactive component: propylamine;

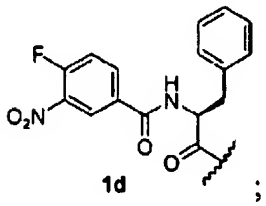
g.) successive reactive component: SnCl2;

h.) additional reactive components: piperidine;

i.) nucleophilic substitution;

j.) protein kinase as the target;

k.) scaffold:



1d ;

l.) F and NO2 as scaffold functional groups;

m.) scaffold linker: Met;

Applicants further state "Claims 1-7, 12, 15-18, 20 and 29 are readable" on the elected species. (Reply, 4/9/07; p. 12, top). Accordingly, Claims 8-11, 13-14, 19, 21, and 28 are withdrawn due to non-elected species. . In addition, the nonelected species are withdrawn from each corresponding claim.

Priority

6. This application claims benefit of provisional application 60/458,470 filed on 03/28/2003.

Information Disclosure Statement

7. The information disclosure statement filed 7/11/05 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein regarding the references listed as numbers 5, 6, 15, 30, 35, 37, 45, 50 and 57 has not been considered. See the attached PTO 1449 form for additional information.

Specification

8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. MPEP 608.01.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description Rejection

10. Claims 1-7, 12, 15-18, 20 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite a method for preparing a library of compounds, comprising: a) providing a plurality of individual synthesis templates each comprising a solid support, wherein said solid support has an interior portion and an exterior portion each with a plurality of reactive functional groups, wherein said solid support is linked to a scaffold via a scaffold linker, wherein said scaffold has at least two scaffold functional groups, and wherein at least two coding tag precursors, each comprising a coding functional group and a coding linker, are attached to said solid support; b) contacting a first synthesis template with a first reactive component such that a first scaffold functional group reacts with said first reactive component to afford a first scaffold building block, and a first coding functional group reacts with said first reactive component to afford a first coding building block; c) contacting said first synthesis template with a successive reactive component such that a subsequent scaffold functional group reacts with said successive reactive component to afford a subsequent scaffold building block, and a subsequent coding functional group reacts with said successive reactive component to afford a subsequent coding building block; d) repeating step c) until said first compound has been prepared; and e) subjecting additional synthesis templates to steps b) - d) with additional reactive components to prepare said library of compounds.

To satisfy the written description requirement, applicants may convey reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.

Applicants may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. See, e.g., Vas-Cath, 935 F.2d at 1565, 19 USPQ2d at 1118.

The written description requirement of 35 U.SC. 112 exists independently of enablement requirement, and the requirement applies whether or not the case involves questions of priority. The requirement applies to all inventions, including chemical inventions, and because the fact that the patent is directed to method entailing use of compound, rather than to compound per se, does not remove patentee's obligation to provide a description of the compound sufficient to

distinguish infringing methods from non-infringing methods. See Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 920-23, 69 USPQ 2d 1886, 1890-93 (Fed. Cir. 2004).

With regard to the description requirement, applicants' attention is invited to consider the decision of the Court of Appeals for the Federal Circuit, which holds that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it form other materials." University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1405 (1997), quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original) [The claims at issue in University of California v. Eli Lilly defined the invention by function of the claimed DNA (encoding insulin)].

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species or by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical an/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F. 3d at 1568, 43 USPQ2d at 1406.

The instant claims (especially Claim 1) are drawn to a genus of method of making a library compounds using various components. The instant specification broadly defines the various components including "library of compounds" (p. 6; [0022]), "compound" (p.6, [0023]), "synthesis template" (p.7, [0025]), "scaffold functional group" (p.7, [0027], etc. Each of the

terms is broadly defined to encompass almost any chemical entities. For example, the term "reactive component" is defined as "a chemical or reagent that is used to modify a functional group into a building block" *[sic]* (p.7, [0031]). Thus, the "reactive component" can be any reactive chemical entity. The instant claims are, therefore, drawn to any chemicals. Neither the instant specification nor the claims have demonstrated common structure and/or function for the claimed genuses of "scaffold functional groups", "synthesis template", "compound", "reactive component", "linkers", etc. In addition, no representative number of species for each claimed genus is provided to show possession of the claimed genuses.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. (see MPEP 2163 II).

In this case, the only examples provide are "peptides" or amino acids as the synthesized testing compounds, and peptides as the coding compounds, as well as certain small organic molecules as the testing compounds (but not the coding compounds). These examples do not provide representative number of species to indicate possession of the entire genus of methods of making any compound using any reactants.

Thus, Applicants' claims encompass compounds created from every element in the periodic table combined in every conceivable way. However, this enormous scope cannot be justified. For Example, Lauf et al. state, "The preparation of new materials with novel and useful chemical and/or physical properties is at best unpredictable considering current levels of

understanding. Consequently, the discovery of new materials depends largely on the ability to synthesize and analyze new compounds. Given approximately 100 elements in the periodic table, which can be used to make compositions consisting of three, four, five, six or more elements, the universe of possible new compounds remains largely unexplored" (e.g., see U.S. Patent Application Pub. No. 2004/0062911 A1, page 1, paragraph 4). See also Young et al. state, "For a given [combinatorial] reaction or sequence of reactions, the number of possible products can be astronomical ... it is impossible to make all possible products. Even with a two-component reaction with a modest number of building blocks, it generally does not make economic sense to build all the products, as there may be more than can be afforded and many may be largely redundant" (see Young et al., "Design of Diverse and Focused Combinatorial Libraries Using an Alternating Algorithm" J. Chem. Inf. Comput. Sci. 2003, 43, 1916-1921, especially page 1916, column 1, paragraphs 1 and 2).

Even in a narrowing scope of using only amino acids as building blocks for the instant claimed method, high unpredictability exist for generating any peptide using any amino acid and any coding building blocks. For example, Liu et al (J. Am. Chem. Soc. Vol. 124: 7678-7680; 2002; cited in IDS) teaches several limitations of a similar encoding method as the instant claims. The Liu reference teaches "synthetic conditions of the small molecule, peptide tag, and scaffolding have to be compatible with each other and (2) building blocks need to be carefully chosen so that the retention times of their amino acid derivatives do not overlap". (p. 7680, left col.). The reference also teaches that the stability of the peptides is a necessary condition for the coding compound (p. 7680, left col., top). Thus, it is not known in the art nor disclosed in the

instant specification that any test compound (with its coding compound) can be generated from any precursor (or building block) compound.

The recited method of producing a library of compounds is essentially a trial and error process that would involve identifying compatible testing compound building blocks and coding compound building blocks. Without identifying the required precursor molecules that can be used to establish the library of compounds that can be generated in parallel with the coding compounds, the claimed method of producing the desired library compounds cannot be accomplished.

Therefore, applicants are not in possession of the entire claimed genus of method of generating any compound from any precursor molecules.

Second paragraph of 35 U.S.C. 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-7, 12, 15-18, 20 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "said first compound" in step d). There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the phrase "wherein at least two coding tag precursors", which is not clear as to which part of the "synthesis template" the coding tags are attached to. It is not clear if the

coding tags are attached to the "scaffold" or if the tags are attached elsewhere on the solid support.

Claim 2 recites the limitation "said compounds". There is insufficient antecedent basis for this limitation in the claim. The instant claim 1 (to which Claim 2 depends on) recites various compounds (such as "a library of compounds", "synthesis template", "functional groups", "tag precursors", "first reactive components", "first compound", etc.). It is not clear to which "compounds" the said term is referring.

Claim 5 recites the limitation "said compounds". There is insufficient antecedent basis for this limitation in the claim. The instant claim 1 (to which Claim 5 depends on) recites various compounds (such as "a library of compounds", "synthesis template", "functional groups", "tag precursors", "first reactive components", "first compound", etc.). It is not clear to which "compounds" the said term is referring.

Claim 16 recites the limitation "said compounds". There is insufficient antecedent basis for this limitation in the claim. The instant claim 1 (to which Claim 16 depends on) recites various compounds (such as "a library of compounds", "synthesis template", "functional groups", "tag precursors", "first reactive components", "first compound", etc.). It is not clear to which "compounds" the said term is referring.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(Note: the instant claim numbers are in bold font.)

Lebl

14. Claims 1-7, 12, 15-18, 20 and 29 are rejected under **35 U.S.C. 102(b)** as being anticipated by Lebl et al (US 5,840,485; 11/24/1998; cited in IDS).

The instant claims recite a method for preparing a library of compounds, comprising: a) providing a plurality of individual synthesis templates each comprising a solid support, wherein said solid support has an interior portion and an exterior portion each with a plurality of reactive functional groups, wherein said solid support is linked to a scaffold via a scaffold linker, wherein said scaffold has at least two scaffold functional groups, and wherein at least two coding tag precursors, each comprising a coding functional group and a coding linker, are attached to said solid support; b) contacting a first synthesis template with a first reactive component such that a first scaffold functional group reacts with said first reactive component to afford a first scaffold building block, and a first coding functional group reacts with said first reactive component to afford a first coding building block; c) contacting said first synthesis template with a successive reactive component such that a subsequent scaffold functional group reacts with said successive reactive component to afford a subsequent scaffold building block, and a subsequent coding functional group reacts with said successive reactive component to afford a subsequent coding building block; d) repeating step c) until said first compound has

been prepared; and e) subjecting additional synthesis templates to steps b) - d) with additional reactive components to prepare said library of compounds.

Labl et al, throughout the patent, teach using solid substrate comprising an interior and an exterior for synthesis of various compounds including "coding molecules" and "synthetic test compound". (See Abstract)

The instant claimed invention and the corresponding teachings of the reference are as follows (with the instant claim recitation in *Italic*):

For claim 1: *a) providing a plurality of individual synthesis templates: solid support has an interior portion and an exterior portion*: The reference teaches solid support comprising an interior portion and an exterior portion (such as surface portion) (e.g. Claim 1; Figure 1; col. 6, lines 11+).

each with a plurality of reactive functional groups: The reference also teaches the exterior and the interior of the beads (solid support0 comprise various functional groups. (e.g. col. 12, lines 15+)

wherein said solid support is linked to a scaffold via a scaffold linker, wherein said scaffold has at least two scaffold functional groups: The reference teaches the solid support comprise a "scaffold molecule" comprising at least two functional groups such as the ones contained by amino acids (modified or otherwise) (e.g. Claims 6 and 8; col. 12, lines 50+). The reference also teaches various linkers to link the various functional groups to the solid support. (e.g. cols. 12-13).

wherein at least two coding tag precursors, each comprising a coding functional group and a coding linker, are attached to said solid support: The reference teaches the "coding molecule is a branched polypeptide" (e.g. Claim 11; Figure 1), and "on each said support, the structure of the test compound is encoded by a plurality of species of coding molecules" (e.g. claim 13), which read on the "at least two coding tag precursors" of the instant claim.

b) contacting a first synthesis template with a first reactive component such that a first scaffold functional group reacts with said first reactive component to afford a first scaffold building block, and a first coding functional group reacts with said first reactive component to afford a first coding building block: The reference teaches chemically linking subunits (read on reactive components) to the scaffold (or synthetic test compound) and the coding molecule (e.g. cols. 10-11; especially, col. 10, lines 55+; col.11, lines 36+).

c) contacting said first synthesis template with a successive reactive component such that a subsequent scaffold functional group reacts with said successive reactive component to afford a subsequent scaffold building block, and a subsequent coding functional group reacts with said successive reactive component to afford a subsequent coding building block; d) repeating step c) until said first compound has been prepared; and e) subjecting additional synthesis templates to steps b) - d) with additional reactive components to prepare said library of compounds: The reference teaches repeating the synthesis steps and creating polymers (e.g. col. 11, lines 21+; col.6, lines 46+).

For Claim 2: The reference teaches cleaving the synthetic compounds from the solid support (col.34, lines 35+), which reads on the cleaving step the instant claim.

For Claim 3: The reference teaches elongating the same polymer on the "test arm" as the "coding arm" (col. 11, lines 36+), which reads on the same number of functional groups of instant claim.

For Claim 4: The reference teaches nucleophilic displacement reactions (e.g. claim 23; col.79, 13+), which reads on the nucleophilic substitution of the instant claim.

For Claim 5: The reference teaches parallel synthesis of the coding and the test compounds (e.g. col. 11, lines 10+) and the generation of a library of test compounds together (e.g. cols. 10-11), which read on the parallel synthesis of the compounds of the instant claim.

For Claim 6: The reference teaches general formula for the solid support comprising synthetic compounds and coding compounds such as depicted in Figure 1 (especially Figure 1C comprising an interior and en exterior), and as depicted in cols. 41-42. For example, the schematic diagram of cols. 41-42 shows linkers for both the coding and the testing strands (reads on "L" and "L'" of instant formula I), a double circled region as the solid support (interior and exterior of formula I), functional groups protected by Fmoc (reads on "$(G^{i})n$" of formula I) as well as Boc and Alloc protection groups (read on "$(G')^{i}$" of formula I).

For Claim 7: The reference teaches the "coding molecule is a branched polypeptide" (e.g. Claim 11; Figure 1), and "on each said support, the structure of the test compound is encoded by a plurality of species of coding molecules" (e.g. claim 13). The reference also teaches multiple numbers of coding molecules are attached to the insides of individual resin beads (i.e. the solid support) (e.g. col.16, lines 7+). Thus, the multiple coding molecules on the same resin bead read on the "L'-$(G')^{2}$" and the "L'-$(G')^{1}$" of the instant Claim 7. The reference

also teaches multiple (at least two) test compounds linked to the "scaffold" (e.g. Figures 3-4; col. 28), which read on the "G1" and "G2" groups of formula Ia of the instant claim.

For Claim 12: The formula III depicted in the instant claim 12 is essentially the same as the formula (I) of the instant claim 6. Thus, the reference's teaching as discussed above read on the instant claim.

For Claims 15 and 29: The reference teach each coding subunit correspond to a test compound subunit (e.g. cols.9-10; especially, col.10, lines 4+; col.6, lines 34+).

For Claim 16: The reference teaches a decoding step by cleaving the coding compounds such as peptides from the solid support and sequence the peptide (e.g. col.37, lines 5+), which reads on the decoding step of the instant claim.

For Claim 17: The reference teaches using mass spectrometry to determine the synthesized compounds or coding compounds. (e.g. cols.6-7, bridging para; col.33, lines 22+).

For Claim 18: The reference teaches using one type of scaffold to generate a library of different compounds (e.g. Figures 7 and 8; col.7, lines 60+).

For Claim 20: The reference teaches using compounds such as amino acids, and polyaromatic structures as scaffolds (e.g. Figure 3; Claims 37-89), which read on the elected scaffold species of the instant claim 20.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SL/
Art Unit 1639
6/22/07

/Jon D. Epperson/

Primary Examiner, AU 1639